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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61B 18/20		A2	(11) International Publication Number: WO 00/54685
			(43) International Publication Date: 21 September 2000 (21.09.00)
(21) International Application Number: PCT/US00/06563		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).	
(22) International Filing Date: 13 March 2000 (13.03.00)		Published <i>Without international search report and to be republished upon receipt of that report.</i>	
(30) Priority Data:			
09/270,118 15 March 1999 (15.03.99) US 09/357,745 20 July 1999 (20.07.99) US 09/393,830 10 September 1999 (10.09.99) US			
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(54) Title: HAIR REMOVAL DEVICE AND METHOD			
(57) Abstract			
<p>A hair removal device (22) includes a cooling surface (34) which is used to contact the skin (6) prior to exposure to hair tissue-damaging laser light (74) passing from a radiation source (36) through a recessed window (46). The window is laterally offset from the cooling surface and is spaced apart from the cooling surface in a direction away from the patient's skin to create a gap between the window and the skin. The window preferably includes both an inner window (46) and an outer, user-replaceable window (48). The laser-pulse duration is preferably selected according to the general diameter of the hair.</p>			

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HAIR REMOVAL DEVICE AND METHOD

BACKGROUND OF THE INVENTION

5 Use of light to denature very specific kinds of tissue has been called wavelength-selective photo-thermolysis. The use of lasers for this purpose has been well described in the literature. See, for example, R.G. Wheland, "Laser-assisted hair removal", Lasers in Dermatology, Vol. 15, pp. 469-477, and references cited. By choosing a laser with the right wavelength and energy per unit area (fluence), a particular
10 light-absorbing target substance (chromophore) in living tissue, such as melanin or hemoglobin, will absorb energy from the laser beam and become hot enough to destroy functionality in the tissue containing the chromophore. Tissue in the same area that does not have high concentration of the target chromophore will not be affected.

 Hair includes two basic parts, the shaft, which is the portion of the hair
15 above the epidermis, and the root, which is the portion below the surface of the epidermis. Various tissues surround the root of the hair. Hair color is primarily do to the presence of melanin in the hair. Melanin is created at the base of the hair follicle and is passed into the hair as it grows. The presence of melanin has made it possible to use lasers and other light sources for hair removal with melanin as the target chromophore. The hair follicle
20 and surrounding structure (referred to collectively as hair tissue) are selectively heated when the melanin in the hair tissue and in the hair root itself and is exposed to treatment radiation. The hair tissue is thermally damaged so that a result of the localized heating, many of the exposed hairs later atrophy and are sloughed from the epidermis.

 The early work in this field was centered around a wavelength with very
25 high melanin absorption, the pulsed ruby laser (694nm). Long pulse ruby lasers (as opposed to Q-switched ruby lasers) typically have a pulse duration in the 1 millisecond range. Although the wavelength is highly absorbed in melanin, the wavelength selection has significant limitations with darker skin types as the epidermis can blister from the superficial melanin heating.

30 Many different approaches to hair removal have been explored since the early ruby laser evaluation. A common trend is a continual shift towards longer wavelengths, which have less melanin absorption, as it allows treatment of patients with a

darker range of skin tones. Initially, alexandrite (755nm) was evaluated and later a diode approach (810nm). The alexandrite laser offers improved clinical capabilities over the ruby laser if one considers treatment of darker skin types. However, from engineering and system performance measures, the two systems are similar in terms of size, utility requirement, treatment speed, and system cost. In contrast, the high pulse energy diode laser allows the system to be much smaller than previous systems with an ability to run off of standard power. One commercially-available system, sold by Coherent of Santa Clara as Lightsheer, weighs in the 45kg (100 pound) range and allows the physician to treat the darkest skin types with minimal risk of post operative blistering. Unfortunately, the high pulse energy diode approach is very expensive as it requires up to 100 diode bars to achieve the peak powers needed for the desired clinical result. Another limitation with this approach is in the delivery device. The current Lightsheer system houses all diodes and associated hardware in a handpiece that is used in direct contact with the skin. This approach results in a heavy handpiece, weighing several pounds, that causes user fatigue and an overall bulky design.

Dermatologists have used cooling devices in dermatologic applications prior to laser treatment. The purpose is to chill the skin with the understanding that exposure to treatment radiation will elevate the epidermal temperature. Chilling lowers the initial temperature so that the post treatment temperature at the epidermis will not create a heat-induced blister. U.S. Patent 5,735,844 describes apparatus which uses a cooled lens, through which radiation passes, pressed against the patient's skin to cool the epidermis.

SUMMARY OF THE INVENTION

The present invention is directed to a hair removal device and method by which hair tissue-damaging radiation passes from a radiation source through a recessed window to the patient's skin. The hair removal device also includes a skin-cooling element having a cooling surface which is used to contact the skin prior to exposure of that skin area to the radiation. The window is laterally offset from the cooling surface as well as spaced apart from the cooling surface in a direction away from the patient's skin so to create a gap between the window and the patient's skin.

The presence of a gap between the window of the radiation source and the patient's skin offers several benefits. One problem associated with a contact cooling window in direct contact with the skin is debris build up. Dermatologic tissue

accumulates on the contact window as treatment pulses are delivered. The window must be periodically wiped in order to preserve the window from local, intense overheating that thermally and mechanically stresses the window and causes pitting. A recessed window does not exhibit this problem. Another advantage is that the window can be kept warm and above the local dewpoint temperature for both the inner and outer surfaces, so water and other condensables do not collect on it. Since the window is not in contact with the skin, it does not cause any re-heating of the pre-cooled skin.

In one embodiment of a hair removal device the radiation source includes an optical chamber having an exit aperture covered by the recessed window and an optical fiber entrance in which an optical fiber can be housed to permit tissue-damaging radiation to pass from the optical fiber into the optical chamber. The optical chamber may have reflective sidewalls to help equalize radiation fluence; a total internal reflecting optical element, such as a fused silica block, may be used to reduce losses. The optical chamber may also be heated to help prevent condensation from forming on the walls of the chamber or the window. A moisture wicking element may be used to wick condensation away from cooled surfaces adjacent the optical chamber to a heat sink or other heated element where the moisture evaporates. The window may include both an inner window and an outer, user-replaceable window; if the outer window becomes damaged through use, it can be easily replaced without affecting the integrity of the optical chamber. This is an advantage over fixed, single window designs that are rendered unusable if there is a surface imperfection due to, for example, localized pitting.

The hair removal device may be coupled to a laser which supplies laser light to the radiation source for passage through the recessed window. The laser may be controlled by user-operated laser power inputs including a laser-pulse duration input and one of a laser-pulse amplitude input and a laser-pulse fluence input. The laser-pulse duration input may be adjusted according to the diameter of the hair, which corresponds to the thermal relaxation time of the hair. Therefore, smaller diameter hairs will typically call for shorter laser-pulse duration inputs while larger diameter hairs will call for a longer laser-pulse duration inputs. Although larger diameter hairs will be selectively heated with short pulses, defined as a pulse duration shorter than the thermal relaxation time of hair, the peak power on the epidermis is unnecessarily higher than it needs to be. This can result in a heat-induced blister.

Another aspect of the invention relates to a method for preparing a hair-removal device for use including the steps of (1) determining the diameter typical of the hair to be removed, and (2) selecting a laser-pulse duration for a hair removal device according to this diameter of the hair so that smaller diameter hair results in a shorter laser-pulse duration than larger diameter hair. This aspect may be supplemented by the step of (3) applying laser energy through a window of a hair removal device of the selected laser-pulse duration to a patient's skin to cause thermal injury to hair tissue. This applies to both individual hairs and a plurality of hairs.

The methods may include selecting a chosen one of a laser-pulse amplitude and a laser-pulse fluence prior to the applying step. Further, the hair-removal method may also include positioning a cooling element of the hair removal device against a first target area and then moving, after a period of time, the cooling element from the first target area to a second target area so that the window overlies and is spaced apart from the first target area; laser energy is then applied to the first target area through the window with the window overlying and spaced apart from the first target area.

The pulse duration has been shown to have significant clinical implications. A short pulse, typically in the sub-5ms, range creates high peak powers because high fluence is required to deliver enough energy to achieve the proper clinical endpoint. High peak power tends to heat the epidermis. Longer pulses result in lower peak power.

Shorter wavelengths, such as 694nm, do not penetrate deeply into the patient's skin so, some believe, that it may be desirable, with such shorter wavelengths, to use a convex window pressing against the skin to shorten the path from the window to the hair tissue as is taught by U.S. Patent No. 5,735,844 patent. It has been found that by the use of longer wavelengths which are still absorbed by melanin, such as 800 to 1200nm, it is not necessary for the window of the radiation source to press against the patient's skin to effectively irradiate the hair tissue at a target area.

Another aspect of the invention is the recognition that it is not necessary to cool the skin the same time it is being irradiated. This is because once the skin has been cooled through contact with a cold surface, removal of the cold surface permits the skin to warm up but it does so much more slowly than it has cooled down because it is relying almost entirely on convection rather than conduction. Recognizing the fact that the skin remains sufficiently cool for a second or two after removal of the cooling surface permits

the window of the radiation source to be positioned spaced apart from the surface of the skin. This eliminates some problems created when the window of the radiation source directly contacts the skin during irradiation, such as window surface damage caused by intense heating from hair fragments that are heated by the laser beam.

5 A further aspect of the invention is the recognition that radiation in the longer wavelengths (about 800 to 1200nm) of the band of melanin-absorbing radiation, typically considered from about 600nm to 1200nm, can be used without the need for the use of chromophore contaminants as taught by U.S. Patent 5,425,728.

Other features and advantages of the invention will appear from the
10 following description in which the preferred embodiments have been set forth in detail in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a simplified cross-sectional view of a hair with its root within a
15 hair follicle;

Fig. 2 plots absorption coefficient versus wavelength for different substances including melanin;

Fig. 3 is a schematic representation of a hair removal assembly made according to the invention;

20 Fig. 3A is a simplified side view of the hair removal device of Fig. 3 with portions broken away to show internal detail;

Fig. 3B is a simplified cross-sectional view taken along line 3B-3B of Fig. 3A;

Fig. 4 is a bottom plan view of the hair removal device of Fig. 3A;

25 Fig. 4A is an overall view of the lower end of an alternative embodiment of the hair removal device of Fig. 3A;

Fig. 5 is a theoretical plot of fluence versus radial position for a diverging beam;

Fig. 5A shows an idealized plot of how to square off or equalize the
30 fluence of the beam of Fig. 5;

Fig. 6 is a simplified view of the radiation source of Fig. 3 showing how radiation is reflected from the walls of the reflective chamber to help equalize radiation intensity and reduce hot spots;

Fig. 7 shows several idealized plots of temperature versus depth below the skin surface;

Figs. 8A, 8b, 8C and 8D are two isometric views, a top plan view and an end view of another alternative embodiment of the hair removal device of Fig. 3A with the ergonomically shaped body removed;

Fig. 9 is a simplified partial cross-sectional view of an alternative embodiment of the hair removal device of Fig. 3A in which the device is configured to permit the user to see the skin area being treated;

Fig. 10 is a simplified view of the bottom of a further alternative embodiment of the hair removal device of Fig. 3A showing leading and trailing cooling surfaces;

Fig. 11 is a partial cross-sectional side view of a hair removal device similar to that of Figs. 8A-8D but including a total internal reflecting optical element to help reduce laser radiation losses;

Fig. 12 is an embodiment similar to that of Fig. 11 but also including a moisture wicking element to help remove condensation which may be produced along the reflecting chamber adjacent to the cooled copper block; and

Fig. 13 is a simplified cross-sectional view taken along line 13-13 of Fig. 12.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Fig. 1 illustrates, in simplified form, a hair 2 including a shaft 4 extending above skin surface 6 and a root 8 extending below the skin surface. The root 8 passes through epidermis 10 into dermis 12 with the base of the root being about 4mm below surface 6. Root 8 is housed within hair follicle 14, hair follicle 14 being surrounded by various tissues including connective tissue sheath 16 and blood vessels 18. The various tissues closely surrounding root 8 and connected with the growth of hair 2, including hair follicle 14 and connective tissue sheath 16, are collectively referred to as hair tissue 20 in this application.

Because melanin is also present in epidermis 10, with darker skin types having more melanin than lighter skin types, it is important that the wavelength be long enough so that absorption is low for the moderate concentrations in melanin in the epidermis to permit most of the light to pass through to the root 8 and hair tissue 20 where

melanin concentrations are relatively high compared to the epidermis. Therefore, it is preferred to use wavelengths in the 800 to 1200nm range; in particular, an Nd:YAG (neodimium-doped YAG) laser having a wavelength of 1.06 micron is preferred because it is a relatively efficient source and the technology is well developed and readily available.

Fig. 3 illustrates, schematically, a hair removal assembly 21 including a hand-held hair removal device 22, device 22 shown in more detail in the simplified views of Figs. 3A and 3B. Device 22 includes a hand-grippable body 24 having an upper or outer end 26 into which an umbilical cable 28 passes. Body 24 also has a lower or skin contacting end 30 housing a formed copper block 32, block 32 having various cavities to provide various features and functions as described below. Block 32 defines a cooling surface 34, see also Fig. 4, which is used to contact the patient's skin and cool the skin and prior to irradiation. Surface 34 is a low friction, high lubricity surface to help prevent bonding between the cooling surface and the skin.

Copper block 32 also houses a radiation source 36. Radiation source 36 includes a reflective chamber 38, in this embodiment having a square cross-sectional shape. Reflective chamber 38 has its walls covered with a highly reflective material, such as gold; the material is chosen for its reflective qualities for the particular wavelength radiation to be used. Other materials, such as dielectric layers combined with high-reflectivity metals, could also be used. Chamber 38 has an optical fiber entrance 40 to permit an optical fiber 42, or a bundle of optical fibers, to extend into chamber 38. The opposite end of chamber 38 has an exit aperture 44 covered by a recessed window 46. Recessed window 46 is spaced apart from cooling surface 34 by a distance or gap 47, such as about 1 to 3mm (.04 to .12in). Recessed window 46 includes an inner window 48, typically permanently or semi-permanently mounted to copper block 32 at exit aperture 44, and an outer window 50. Outer window 50 is removable secured in place by the use of an clip, not shown, or other suitable means. Windows 48, 50 are made of a suitable material, such as fused silica, although other materials, such as optical glasses, could also be used. By the use of inner and outer windows 48, 50, if outer window 50 is damaged, it can be easily replaced by the user. Accordingly, outer window 50 acts as a sacrificial window which if damaged, such as can occur through spalling as a result of bits of hair exploding when subjected to high power radiation, can be easily replaced.

Cooling surface 34 is cooled through the use of a coolant evaporator 52 housed within a blind bore 54 formed in copper block 32. The coolant, which may be of various commercially available types, commonly Freon® or other fluorinated hydrocarbons, is directed to evaporator 52 through a coolant liquid line 56 and is recycled back to a refrigerant compressor 62 (see Fig. 3) through a coolant vapor return line 58. Line 58 coaxially houses coolant liquid line 56, line 58 being housed within thermal insulation 60. Lines 56, 58 and insulation 60 pass through umbilical cable 28 to refrigerant compressor 62 associated with a control console 64. Alternatively, cooling surface 34 can be cooled by a thermoelectric, Peltier device instead of the coolant evaporator. This, currently preferred, embodiment of the cooling device is discussed below with reference to Figs. 8A-8D.

While it is desired to cool surface 34, such cooling can result in condensation on the surfaces of radiation source 36, in particular on the walls of chamber 38 and on recessed window 46. To help prevent this, a separation slot 66 is made between that portion copper block 32 used to cool surface 34 and that portion of the block used for radiation source 36. An electrical, typically resistive, heating element 68 is positioned along one wall of slot 66, the right wall as shown in Figs. 3A and 3B, while the other, left wall is covered with thermal insulation 70. Heating element 68 is connected to console 64 through a conductor 71 extending along umbilical cable 28. In lieu of resistive heating element 68, the hot side of a thermoelectric type of heating element, such as discussed below with reference to Figs. 8A-8D, could be used.

Laser hair removal treatments are designed to be effective and yet safe. That is, the treatment should cause thermal damage to hair tissue 20 but not substantial damage to surrounding tissue, such as blistering to the skin. To do so the energy per unit area (fluence) of the laser beam 74 at skin surface 6 must be controlled. Part of this control requires that the distance between skin surface 6 and the end of optical fiber 42 be controlled because beam 74 expands as it passes through reflective chamber 38. The distribution of energy across the laser beam at the skin surface should be substantially constant so that no hot spots, which could cause local damage to the epidermis, are created. Also, the individual exposure sites must fit tightly together, commonly called a tiled effect, so that there is little or no overlapping of the exposure sites and, at the same time, little or no area is left unexposed. The simplest shape that meets this tiling requirement is a rectangle. Other shapes can create a tiled pattern but they have other

drawbacks. Reflective chamber 38 and window 46 both have square cross-sectional shapes for efficient and effective treatment.

Fig. 5 illustrates a graph of fluence versus radial position for a diverging beam, such as from optical fiber 42. What is desired is to square off the graph to equalize the fluence over the beam spot. This is suggested in Fig. 5A in which those portions of the beam at the edges are reflected or folded over back into the main portion of the beam to create a generally square wave graph of fluence versus radial position. Fig. 6 illustrates how this is accomplished with the present invention. The walls 72 of chamber 38 are made to be highly reflective of the particular wavelength of radiation. In the preferred embodiment the wavelength is 1.06 micron and surface 72 is provided with a highly reflective gold surface. As suggested in Figs. 5A and 6, the diverging laser beam 74 not only passes directly through window 46 but the edge portions of the beam are reflected off the walls 72 back into the main portion of the beam to create a generally equalized fluence level. Other optical arrangements can be used to help equalize the fluence applied to skin surface 6. For example, various devices called optical integrators or beam homogenizers are well known in the art of laser material processing. The simplicity of the present device is possible because the exit aperture, by virtue of being close to the cooling surface 34, is located close to the target surface.

In another embodiment, shown in Fig. 9, reflective chamber 38, exit aperture 44 and protective window 46A are spaced much further from the skin surface to, for example, give the practitioner a better view of the treatment area 73 through a view port 75. View port 75 may be an open region, as illustrated, or it could include, for example, transparent and/or reflective members to permit direct or indirect viewing of area 73. In this case, a lens system 77 is used between exit aperture 44 and window 46A to make an image of the exit aperture on the skin surface at treatment area 73. With this approach, the size of the exit aperture need not be the same size as the treatment area 73 on the skin surface. The size of treatment area 73 could be made variable by proper selection of the focal length of lens system 77 and the distance between exit aperture 44 and the lens system. This would be useful when it is desired to use the device for other treatments, such as the treatment of varicose veins.

One way to control unwanted thermal damage to the skin is to cool the epidermis. Fig. 7 illustrates several idealized plots of tissue temperature versus depth below the skin surface. Plot A shows the normal variation of temperature versus depth

with the temperature rapidly approaching the normal core temperature of 37°C. Plot B illustrates the temperature at a range of tissue depth following a laser pulse when there has been no prior cooling of the skin. Assuming the energy is high enough to cause thermal damage at a depth of about 2 to 4mm, the typical range of depths need to cause damage to hair tissue 20, the skin surface temperature is hot enough to cause blistering and burning. The blistering and burning range is indicated by region 76, that is above about 68°C, while the temperature needed to cause hair tissue damage is indicated by region 78, that is above about 48°C. Plot C illustrates the result of cooling the skin surface after adequate pre-cooling. Adequate pre-cooling has commonly been found to be created when an copper heat sink, pre-cooled to about 0°C, is applied to the skin surface for about 1 to 2 seconds. Plot D plots temperature versus skin depth immediately after exposing the skin surface, pre-cooled as in the Plot C, to a laser-pulse similar to that which created Plot B. As can be seen, pre-cooling the skin surface results in prevention of burning or blistering the skin while permitting the target tissue, that is hair tissue 20, to be raised to a sufficiently high temperature to cause thermal damage to the tissue. Note that the plots in Fig. 7 are not taken from actual test data but are idealized plots provided to aid understanding the advantages of pre-cooling of the skin.

Several patents discuss surface cooling to prevent tissue damage. See, for example, U.S. Patents 5,057,104; 5,282,789 and 5, 735,844. Coherent of Santa Clara, California sells a diode laser system for dermatological use as the LightSheer. This product provides a hand piece with a cold window through which the laser exposure occurs. To use the device the window is first pressed against the treatment side for a period of time and then the laser beam is fired through the window. One of the problems with this simultaneous cooling technique when applied to laser hair removal is that it takes two to three seconds with the skin in contact with the cooled window to properly cool the skin surface to about 10 to 15°C. Thus, the practitioner must wait for about one to three seconds at each treatment site before firing the laser-pulse.

The present invention eliminates any need to wait prior to firing the laser-pulse by separating the cooling surface and the laser discharge window. As seen in Fig. 4, cooling surface 34 lies adjacent to window 46 in the direction of movement indicated by arrow 80. The width of surface 34 and window 46 are substantially the same while the length of 34 is about twice the length of window 46, that is with the length considered to be in the direction of arrow 80. Assuming a cooling time of two seconds is desired, the

forward end 82 of cooling surface 34 is placed over the first target area on skin surface 6. After about one second in that position, device 22 is moved in the direction of arrow 80 the length of recessed window 46; in the preferred embodiment this is about one centimeter. At this time the first target area shifts to a position covered by cooling surface 34 but adjacent to window 46. After a second one-second interval, device 22 is again moved the length of recessed window 46; at this time the first target area, which has been cooled for a total of about two seconds, is aligned with recessed window 46. The practitioner then presses a fire button 84 on body 24 of device 22 causing a laser-pulse to be directed at skin surface 6. The practitioner then continues moving device 22 and pressing fire button 84 at one-second intervals to provide the desired laser treatment of the skin surface.

The desired two-second cooling of skin surface 6 could also be done with cooling surface 34 about the same size as window 46. To do so would require that device 22 be moved only every two seconds, or some other length of time needed to cool the skin surface 4. By making cooling surface 34 with a length greater than the length of window 46, the amount of time between laser-pulses need not be controlled by how long it takes to cool the skin surface. Rather, the device can be designed so that the time between laser-pulses is chosen to be at a comfortable pace for the operator while not unduly extending the time the entire procedure takes. For example, if it is believed that the proper interval between pulses is three-quarters of a second but the skin area needs to be cooled for three seconds, the length of cooling surface 34 could be made to be about four times the length of window 46; using these parameters, moving device 22 by the length of window 46 between each pulse permits the skin surface to be cooled for the desired three seconds while the practitioner can operate the fire button at the desired three-quarter second between pulses. Therefore, the length of the cooling surface (Y) is equal to the length of the window (X) multiplied by the time desired to cool the target site (C), the result divided by the desired interval between laser pulses (Z); that is, $Y = (X \times C) / Z$. Adjustments to the thermal capacity, thermal conductivity and temperature of block 30 and cooling surface 32 can also be made to vary the required time needed to cool skin surface 6.

Fig. 4A illustrates an alternative embodiment of the invention in which window 46A is rectangular having a width about three times its length. In this case cooling surface 34A would have a width about equal to the width window 46A.

However, the length of cooling surface 34A is, like in the embodiment of Fig 4, about twice the length of window 46A based on the premise that the interval between actuation of fire button 84 will be equal to one-half the length of time it is desired to apply equal surface 34A to the skin surface to properly cool the skin surface.

5 The pre-cooling of the skin surface followed by the irradiation is based on the premise that the skin can be cooled relatively quickly compared with the time it takes to warm back to its normal temperature. For example, in one experimental trial using a cooling surface 34 maintained at about 0°C and applying the cooling surface to skin surface 6 for one second lowered the skin surface temperature about 12°C; application for
10 two seconds lowered the skin temperature by about 18°C; application for three seconds lowered the skin temperature by about 20°C. Therefore, two seconds of cooling time appears to be adequate with this particular cooling surface; three seconds of cooling time is better but only marginally so. While one second of cooling time does produce a significant drop in skin temperature, it may not be adequate depending upon various
15 factors, primarily the amount of pigment in the patient's skin, the patient's hair color and other such factors. Accordingly, it is believed cooling times from about one to two seconds, and generally more preferably about two seconds, are expected to produce good results at a reasonable pace with the disclosed embodiment.

 In another mode of operation which could be used by experienced
20 practitioners, the laser system would be set to emit pulses continuously at a constant repetition rate of, for example, 1 Hz. The practitioner would hold the handpiece in continuous contact with the patient's skin and move it at a constant velocity equal to the product of exposure-area length time repetition rate. This will maximize the rate at which the treatment proceeds while still providing adequate skin cooling and complete coverage.

25 Figs. 8A-8D illustrate another alternative embodiment hair removal device 22 but with the ergonomically shaped body shown in Fig. 3 removed. Device 22A is similar to device 22 but instead of using coolant evaporator 52, device 22 uses a thermoelectric device 88, typically a Peltier device. Thermoelectric device 88 has a warm part 85 and a cold part 86 created by the passage of electricity through the thermoelectric
30 device. To remove the heat created at warm part 85, thermoelectric device 88 includes a water cooled copper heat sink 90 having inlet and outlet lines 92, 94. The cold part 86 of device 88 is thermally coupled to copper block 32A by a bar extension 93 of block 32A so to cool cooling surface 34A, block 32A being gold-plated.

Fig. 10 illustrates another embodiment of the invention in which recessed window 46 is centered between two cooling surfaces 34. This provides two advantages: (1) the practitioner can move device 22 in either direction, back and forth, without having to rotate the handpiece, (2) the trailing cooling surface will reduce both pain and trauma to the skin following the laser exposure. This will be particularly important for the treatment of patients with darker skin types.

Fig. 11 illustrates a further embodiment of the invention similar to the embodiment of Figs. 8A-8D and also with the ergonomically shaped body shown in Fig. 3 removed. Reflective chamber 38B of hair removal device 22B includes a total internal reflecting optical element 100 having an entry surface 102 which accepts laser beam 74, an exit surface 104 facing recessed window 46, and a total internal reflecting sidewall surface 106. By partially filling gold-plated chamber 38B with optical element 100, typically a rectangular fused silica block, the same goal of uniform fluence can be achieved with much reduced optical absorption loss. The gold plating on wall 72B still remains important to maintain reflectivity as high as practical for light scattered back from the treated skin. Entry and exit surfaces 102, 104, windows 48, 50 and optical fiber 42 are preferably coated with thin dielectric layers to reduce reflection losses.

Fig. 12 illustrates a slightly modified version of the hair removal device 22B of Fig. 11. Hair removal device 22C has a moisture wicking element 108, typically made of a refractory material such as glass or ceramic fibers that will not be affected by the laser beam if element 108 happens to be struck directly or indirectly by the laser beam. Element 108 is wrapped around the distal end 110 of reflective chamber 38A adjacent to copper block 32A. Element 108 continues along copper block 32A and then up along the side of water cooled heat sink 90C. Water cooled heat sink 90C is warm enough so that condensation which may collect at or near distal end 110 of reflective chamber 38A can be wicked away and evaporated by the heat generated by thermoelectric device 88. Doing so will help keep optically sensitive areas dry and free of conservation. In addition, the evaporation of water will help cool heat sink 90C. It may be necessary or desirable to provide vents or other structure to help remove warm, moist air produced by evaporating moisture from element 108 at heat sink 90C.

One embodiment of the laser system can operate at average power output levels of up to 120 watts delivered to tissue. Under these conditions there is enough absorption of laser power in reflective chamber 38A that it is important to thermally

connect it to a heat sink. One choice would be to connect chamber 38A to the cold part 86 of the thermo-electric cooling assembly. The problem with this configuration is that when device 22C is not delivering laser energy at a high rate, reflective chamber 38A would become cold enough to condense water vapor out of the air and could collect liquid water on sensitive optical surfaces. A better choice of heat sinking chamber 38A is to thermally connect it to water-cooled heat sink 90C. The cooling water can be supplied from the same circulation system used to cool the laser itself; this water is typically cooled by a water-to-air heat exchanger (not shown). When so cooled the cooling water can never be colder than room temperature and is usually at least several degrees to a few tens of degrees C warmer than room temperature. This helps to ensure that the reflective chamber is always above the dew point and therefore incapable of condensing water out of the air.

Thermal coupling of heat sink 90C with chamber 38A is provided by an extension 112 of heat sink 90. Extension 112 passes through a cut-out in a circuit board 116 and contacts a proximal end 118 of reflective chamber 38A. See Figs. 12 and 13. A pair of set screws 120 are used to secure proximal end 118 to extension 112 for stability and to ensure good thermal contact. Heat sink 90 is typically made of copper and chamber 38A is typically made of aluminum so that heat sink 90 keeps chamber 38A warm enough to help prevent condensation on chamber 38A.

Another aspect of the invention relates to the control of the laser-pulse according to the diameter of shaft 4 of hair 2. Part of this selection is based on the belief that laser-pulse duration should be selected to match the thermal relaxation time of the targeted hair. For small diameter hair the pulse should be shorter while for larger diameter hair the pulse should be longer. This belief is used in conjunction with the belief that high peak powers should be avoided. Thus, it is preferred to use longer pulse durations with lower peak powers and to selectively adjust the duration according to the shaft diameter to minimize or eliminate damage to epidermis 10 while not sacrificing heat transfer to hair tissue 20. With this in mind, it is believed that a wavelength in the range of about 800 to 1200nm would be quite suitable for use with the present invention. For the preferred embodiment a wavelength of 1.06 micron has been chosen. The choice of a 1.06 micron laser is beneficial for many reasons. It permits treating of patient having darker pigmented skin than the shorter wavelength lasers commonly used. The 1.06 micron laser is relatively efficient, requires no special cooling and has the ability to create

high pulse energy (such as about 4000 watts in one preferred embodiment) in low duty cycle pulses without large power-consuming support systems. Further the 1.06 micron laser can use flash lamp excitation which can be engineered at a fraction of the cost of high peak power diode lasers.

5 Console 64 is provided with control panel 95 (see Fig. 3) having a number of inputs 96 to provide the desired user control. Inputs 96 include a laser-pulse duration input, which is chosen according to the hair shaft diameter. The laser-pulse duration pulse input could be selected in terms of actual or relative time duration or in terms of actual or relative hair shaft diameter thickness. In addition to the laser pulse duration
10 (hair shaft diameter) input, control panel 96 also includes one or both of a laser-pulse amplitude input or a laser-pulse fluence input. Other inputs to permit other variables to be controlled can also be provided. Console 64 may also include a display 98 to provide the user with information, such as the temperature of cooling surface 34, optimal laser pulse actuation rate, laser-pulse duration selected, etc. In one preferred embodiment
15 control panel 95 includes the following inputs: keyswitch to start the system and turn it off, standby and ready buttons to select the state of operation, controls to select fluence level, pulse width and repetition rate, and emergency-off button; and has the option of displaying the following information: laser and handpiece status (ready/not ready), laser emission indicator, and pulse counter.

20 In use, the operator first determines the general diameter of the hair to be removed from the patient. Then the laser-pulse duration is selected using the appropriate input 96. In one embodiment, typical hair shaft diameters of about 25 to 150 micrometers will result in laser-pulse durations of about 25 to 150 microseconds. The laser-pulse amplitude or laser-pulse fluence is also selected using an appropriate input 96. After
25 ensuring that the temperature of cooling surface 34 has reached the desired operating temperature, the front end 82 of cooling surface 34 is placed on the initial target area on the patient's skin. To ensure full treatment of the entire area of the skin without missing areas or having excessive overlaps in area, the skin area may be temporarily marked with a set of lines or a grid to help guide device 22. Front end 82 of cooling surface 34 is then
30 placed at a first target area on the patient's skin. Cooling surface 34 typically remains in place from about .25 to two seconds. In one preferred embodiment, cooling surface 34 remains in place for one second; after the first second, device 22 is moved in the direction of arrow 80 a distance equal to the length of window 46. After remaining at this position

for one second, the user again moves a distance equal to one window length. At this point the first target area has been cooled for the designed two seconds so the target area can be irradiated by pressing fire button 84 during the next one-second interval.

Following the firing of a laser and the expiration of the one-second interval, the operator
5 again moves device 22 in the direction arrow 80 one window length and presses fire button 84 to irradiate skin surface 6 thus causing thermal damage to hair tissue 20. The thermal damage is intended to cause the hair root area to be denatured so that the hair does not grow back. This procedure continues over the entire treatment area.

Modification and variation can be made to the disclosed embodiments
10 without departing from the subject of the invention as defined in the following claims.

While the invention has been described primarily with reference to hair-treatment methods, it may also be useful for other dermatological application.

Any and all patents, patent applications and printed publications referred to above are incorporated by reference.

WHAT IS CLAIMED IS:

- 1 1. A hair removal device comprising:
2 a body having a skin-contacting end;
3 a skin-cooling element carried by the body and having a cooling surface at
4 the skin-contacting end;
5 a radiation source carried by the body and having a recessed window
6 through which hair tissue-damaging radiation passes to a patient's skin;
7 said recessed window being laterally offset from the cooling surface; and
8 said recessed window being spaced apart from the cooling surface in a
9 direction away from the patient's skin when the cooling surface is contacting the patient's
10 skin so to create a gap between the window and the patient's skin.
- 1 2. The device according to claim 1 further comprising a radiation
2 pulse actuator button carried by the body.
- 1 3. The device according to claim 1 wherein said radiation source
2 comprises an optical chamber having an exit aperture covered by said recessed window
3 and an optical fiber entrance in which an optical fiber can be housed to permit hair tissue-
4 damaging radiation to pass from the optical fiber into the optical chamber.
- 1 4. The device according to claim 3 wherein the exit aperture is
2 rectangular.
- 1 5. The device according to claim 4 wherein the exit aperture is square.
- 1 6. The device according to claim 3 wherein the optical chamber
2 comprises light-reflecting walls which help to equalize the fluence of radiation passing
3 through the exit aperture.
- 1 7. The device according to claim 3 wherein said optical chamber
2 comprises a total internal reflecting optical element having an entry surface facing the
3 optical fiber, an exit surface facing the recessed window and a total internal reflecting
4 sidewall surface so that effectively all radiation entering the entrance surface from the
5 optical fiber passes through the exit surface.

1 8. The device according to claim 7 wherein the optical element
2 comprises a rectangular fused silica block.

1 9. The device according to claim 3 wherein said optical chamber
2 comprises a beam size-defining lens system by which the lateral size of the radiation
3 beam passing through the recessed window can be controlled.

1 10. The device according to claim 3 further comprising a heating
2 element thermally coupled to the optical chamber so to permit heating of at least a part of
3 the optical chamber.

1 11. The device according to claim 10 further comprising a moisture-
2 wicking element extending between a region cooled by the skin-cooling element and the
3 heating element so that condensation at said region can be wicked away for evaporation
4 by the heating element.

1 12. The device according to claim 1 wherein the cooling surface is
2 adjacent to the recessed window and is aligned with the recessed window along a
3 direction of motion.

1 13. The device according to claim 12 wherein the recessed window and
2 the cooling surface have window and cooling surface dimensions along the direction of
3 motion.

1 14. The device according to claim 13 wherein the cooling surface
2 dimension is at least about two times the window dimension.

1 15. The device according to claim 13 wherein the cooling surface
2 dimension is about equal to the window dimension multiplied by a first chosen time
3 interval for cooling the patient's skin, the result divided by a second chosen time interval
4 between applications of the hair tissue-damaging radiation.

1 16. The device according to claim 1 wherein the window comprises an
2 inner window and an outer, user-replaceable window.

1 17. The device according to claim 15 further comprising an user-
2 removable clip releasably mounting the outer window to the body adjacent to the inner
3 window.

1 18. The device according to claim 1 wherein the body is a hand-
2 grippable body.

1 19. The device according to claim 1 wherein the cooling surface is a
2 high lubricity surface to help prevent bonding between the cooling surface and skin.

1 20. The device according to claim 1 further comprising a view port
2 formed adjacent to the recessed window to permit viewing of the patient's skin directly
3 under the recessed window.

1 21. The device according to claim 1 further comprising means for
2 viewing of the patient's skin directly under the recessed window.

1 22. The device according to claim 1 wherein the skin cooling element
2 comprises first and second of said cooling surfaces with the recessed window being
3 located between said first and second cooling surfaces.

1 23. A hair removal assembly comprising:
2 a body having a skin-contacting end;
3 a skin-cooling element carried by the body and having a cooling surface at
4 the skin-contacting end;
5 a radiation source carried by the body and having a window through which
6 hair tissue-damaging radiation passes to a patient's skin;
7 said window being laterally offset from the cooling surface;
8 a laser supplying laser light to the radiation source for passage through the
9 window; and
10 laser-power inputs comprising a laser-pulse duration input and one of a
11 laser-pulse amplitude input and a laser-pulse fluence input.

1 24. The assembly according to claim 23 wherein said window is a
2 recessed window spaced apart from the cooling surface in a direction away from the

3 patient's skin when the cooling surface is contacting the patient's skin so to create a gap
4 between the radiation source and the patient's skin.

1 25. The assembly according to claim 23 further comprising a source of
2 a liquid coolant, and wherein the cooling element comprises a heat sink, a coolant
3 evaporator thermally coupled to the heat sink, a coolant supply line coupling the coolant
4 evaporator to the source of liquid coolant, and a coolant vapor return line coupling the
5 evaporator to the source of liquid coolant.

1 26. The assembly according to claim 25 wherein the source of liquid
2 coolant comprises a refrigerant compressor.

1 27. The assembly according to claim 23 wherein the skin-cooling
2 element comprises a heat sink and a thermoelectric device having a cooled part, thermally
3 coupled to the heat sink, and a heated part.

1 28. The assembly according to claim 27 wherein the heated part of the
2 thermoelectric device is thermally coupled to a second heat sink.

1 29. The assembly according to claim 28 wherein the second heat sink
2 is a liquid-cooled heat sink.

1 30. The assembly according to claim 23 further comprising a heating
2 element thermally coupled to the radiation source.

1 31. The assembly according to claim 30 further comprising a moisture-
2 wicking element extending between a region cooled by the skin-cooling element and the
3 heating element so that condensation at said region can be wicked away for evaporation
4 by the heating element.

1 32. The assembly according to claim 31 wherein the heating element
2 comprises a heat sink portion and said wicking element is in contact with the heat sink
3 portion of the heating element.

1 33. The assembly according to claim 23 wherein said radiation source
2 comprises an optical chamber having an exit aperture covered by said window and an

3 optical fiber entrance in which an optical fiber is housed to permit laser light from the
4 laser to be directed into the optical chamber, and further comprising a heating element
5 thermally coupled to the optical chamber to help prevent condensation on said optical
6 chamber or said window.

1 34. The assembly according to claim 33 wherein the heating element
2 comprises a heat sink portion in physical contact with the optical chamber.

1 35. The assembly according to claim 26 wherein said optical chamber
2 comprises a total internal reflecting optical element having an entry surface facing the
3 optical fiber, an exit surface facing the recessed window and a total internal reflecting
4 sidewall surface so that effectively all radiation entering the entrance surface from the
5 optical fiber passes through the exit surface.

1 36. The assembly according to claim 35 wherein the optical element
2 comprises a rectangular fused silica block.

1 37. The assembly according to claim 26 wherein said optical chamber
2 comprises a beam size-defining lens system by which the lateral size of the radiation
3 beam passing through the recessed window can be controlled.

1 38. The assembly according to claim 26 further comprising a moisture
2 wicking element extending between a region cooled by the skin-cooling element and the
3 heating element so that condensation at said region can be wicked away for evaporation
4 by the heating element.

1 39. A hair-removal method comprising:
2 determining the diameter typical of the hair to be removed from a patient;
3 selecting a laser-pulse duration for a hair removal device according to this
4 diameter of the hair so that smaller diameter hair results in a shorter laser-pulse duration
5 than larger diameter hair; and
6 applying laser energy through a window of the hair removal device of the
7 selected laser-pulse duration to a patient's skin to cause thermal injury to hair tissue.

1 40. A method for preparing a hair-removal device for use comprising:

2 determining the diameter typical of the hair to be removed from a patient;
3 and
4 selecting a laser-pulse duration for a hair removal device according to this
5 diameter of the hair so that smaller diameter hair results in a shorter laser-pulse duration
6 than larger diameter hair.

1 41. The method according to claims 39 or 40 further comprising the
2 step of selecting a chosen one of a laser-pulse amplitude and a laser-pulse fluence prior to
3 the applying step.

1 42. The method according to claim 39 wherein the laser energy
2 applying step is carried out by:
3 positioning a cooling element of the hair removal device against a first
4 target area on the patient's skin;
5 moving, after a chosen cooling period of time, the cooling element from
6 the first target area to a second target area with the window overlying and spaced-apart
7 from the first target area;
8 applying the laser energy to the first target area through the window with
9 the window overlying and spaced-apart from the first target area

1 43. The method according to claim 42 further comprising moving, after
2 the laser energy applying step, the window to overlay the second target area while
3 positioning a second cooling surface against the first target area.

1 44. The method according to claim 42 wherein the moving step is
2 carried out with the chosen cooling period of time being about .25 to two seconds.

1 45. The method according to claims 39 or 40 further comprising the
2 step of selecting a hair removal device using laser energy in the 800 to 1200nm wavelength
3 range.

1 46. The method according to claims 39 or 40 further comprising the
2 step of selecting a hair removal device using laser energy having a wavelength of about
3 1.06 microns.

1 47. The method according to claims 39 or 40 wherein the selecting step
2 is carried out so that hair diameters from about 25 to 150 micrometers result in laser-pulse
3 durations of about 5 to 50 milliseconds.

1 48. A method for preparing to apply hair tissue-damaging radiation to a
2 target site on a patient's skin comprising:

3 accessing a hair removal device having a skin cooling surface and a
4 radiation source with a window through which hair tissue-damaging radiation passes, the
5 skin cooling surface and the window aligned along a direction of motion;

6 selecting a chosen one of:

7 (i) a first chosen time interval (C) for cooling the target site; and
8 (ii) a second chosen time interval (Z) between applications of hair
9 tissue-damaging radiation; and

10 determining the other of the first and second time intervals based on the
11 following:

12 $Y = (X \times C) / Z$, where

13 X and Y are the respective lengths of the cooling surface and the
14 window measured in the direction of motion.

1/8

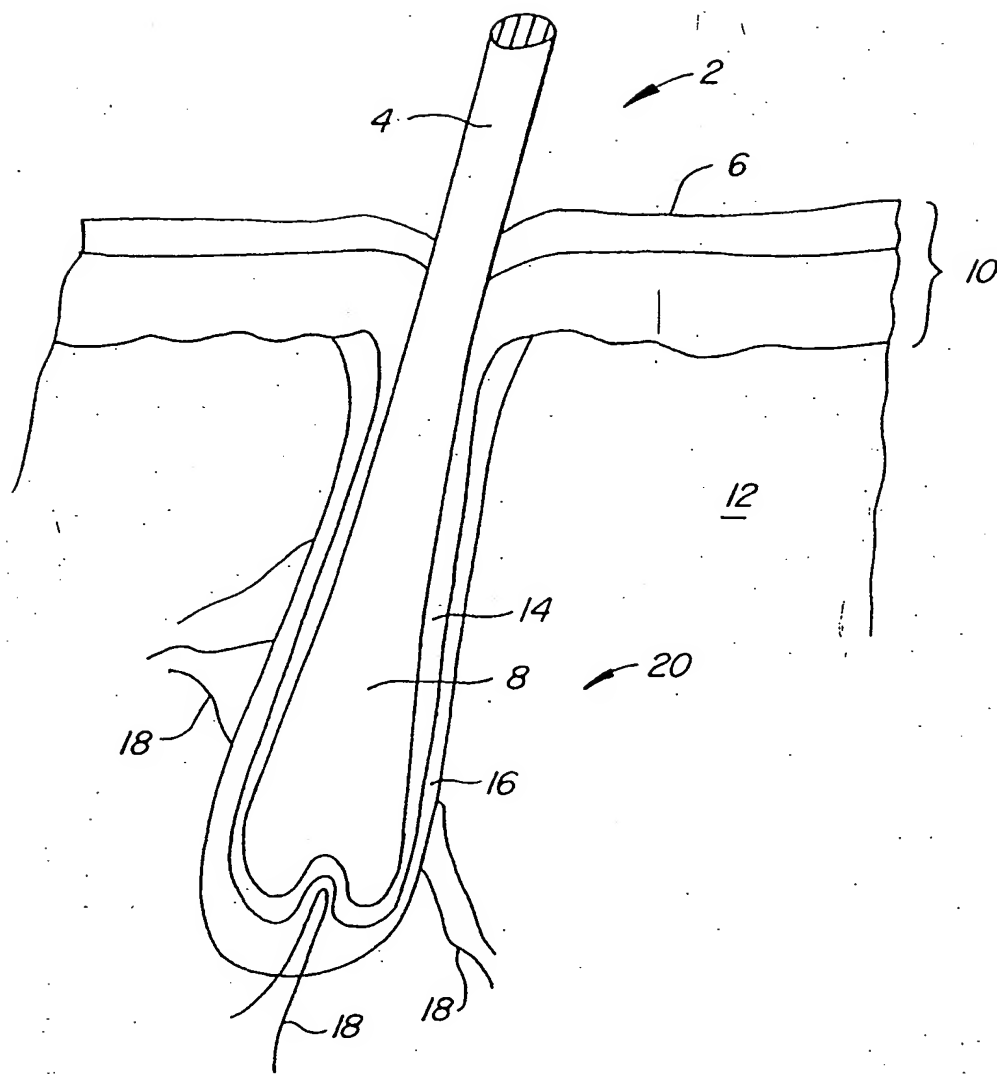


FIG. 1.

2/8

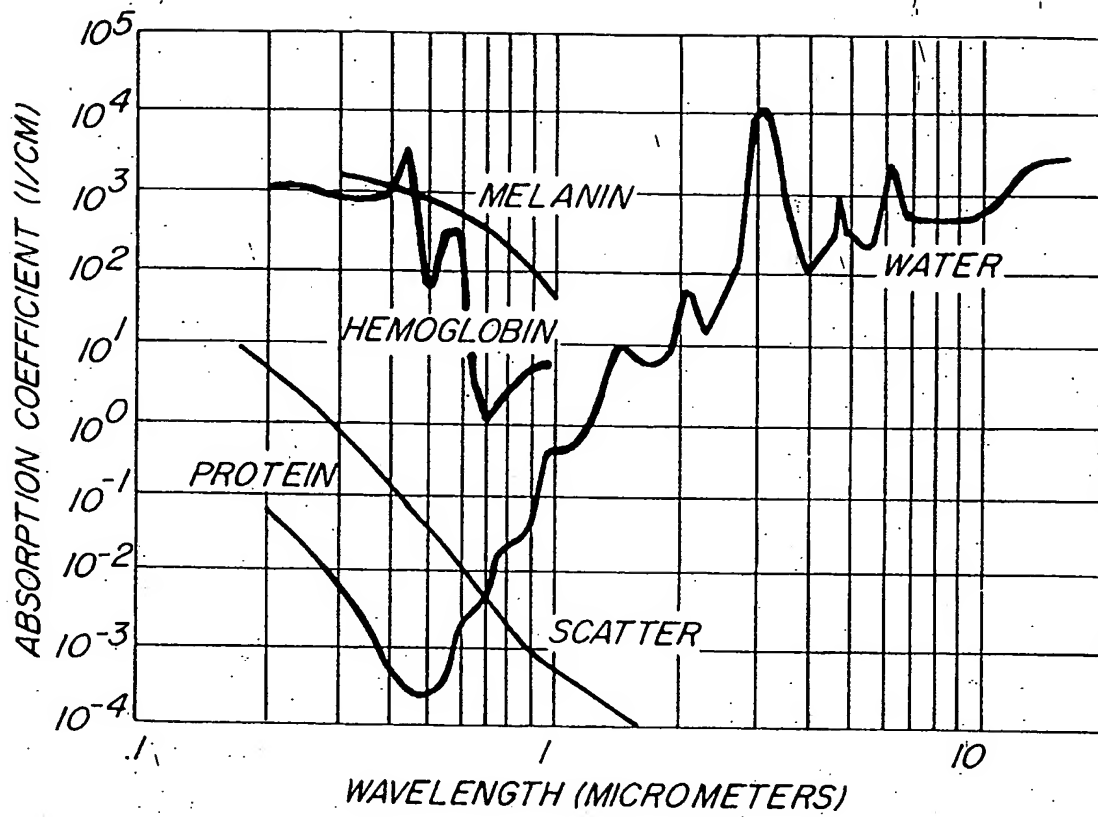


FIG. 2.

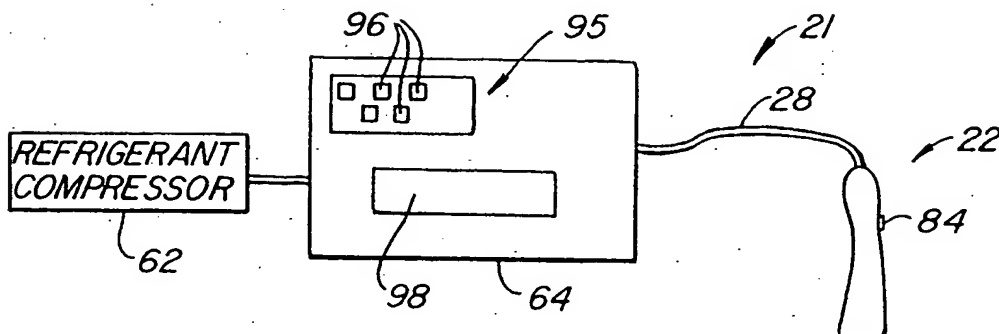


FIG. 3.

3/8

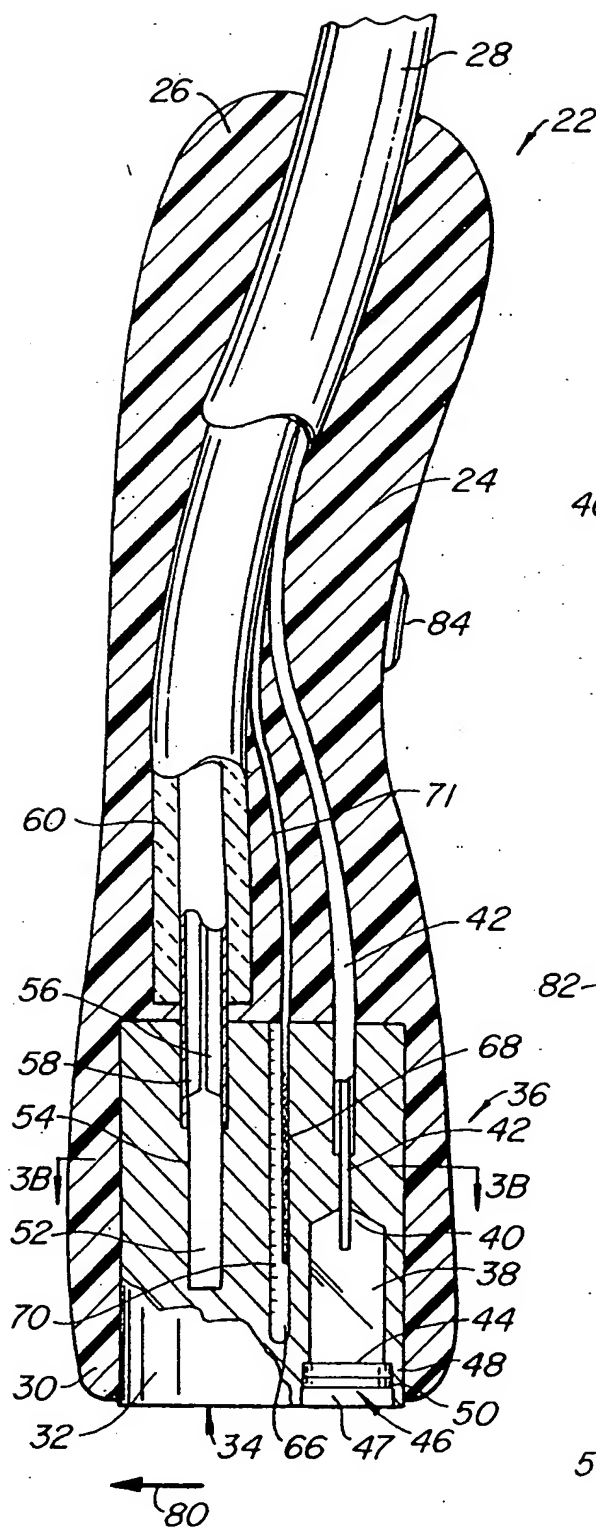


FIG. 3A.

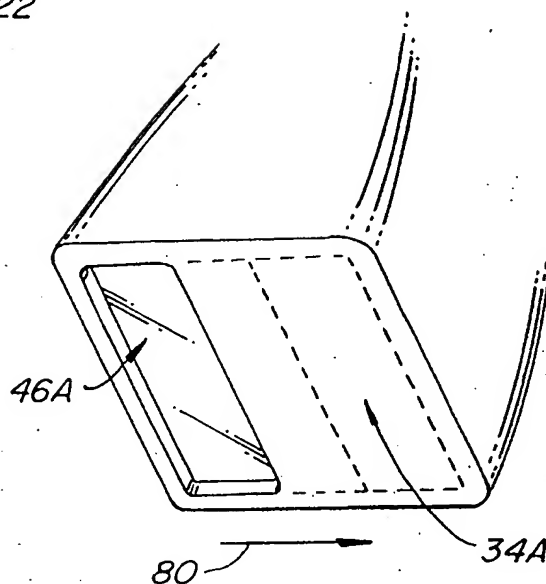


FIG. 4A.

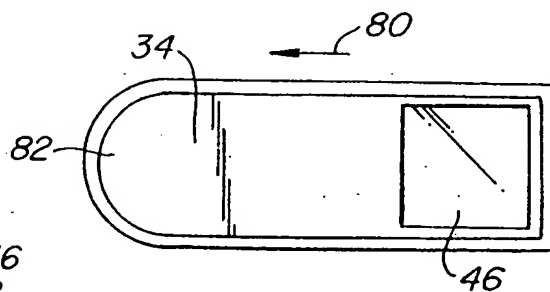


FIG. 4.

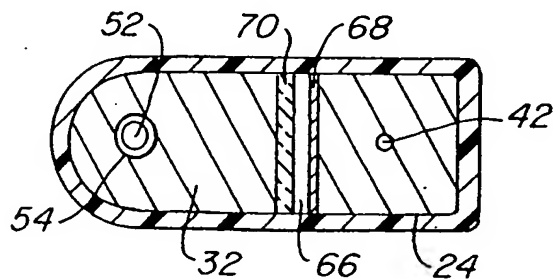


FIG. 3B.

4/8

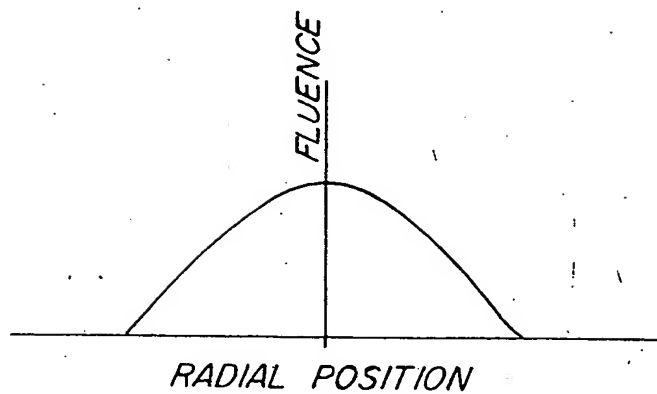


FIG. 5.

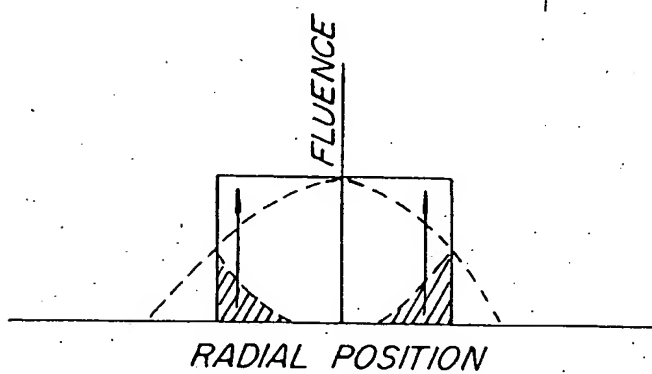


FIG. 5A.

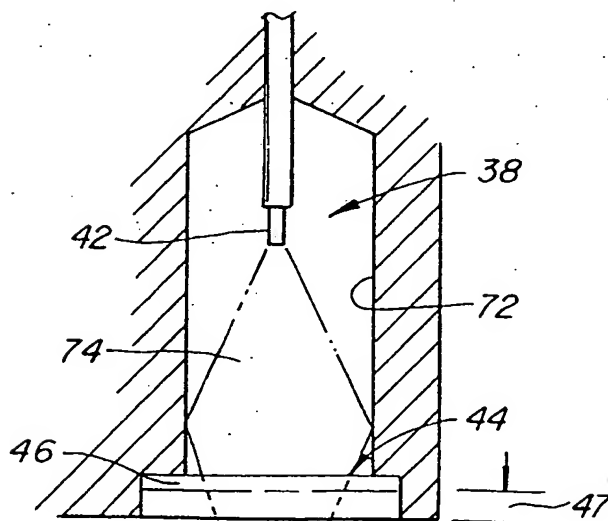


FIG. 6.

5/8

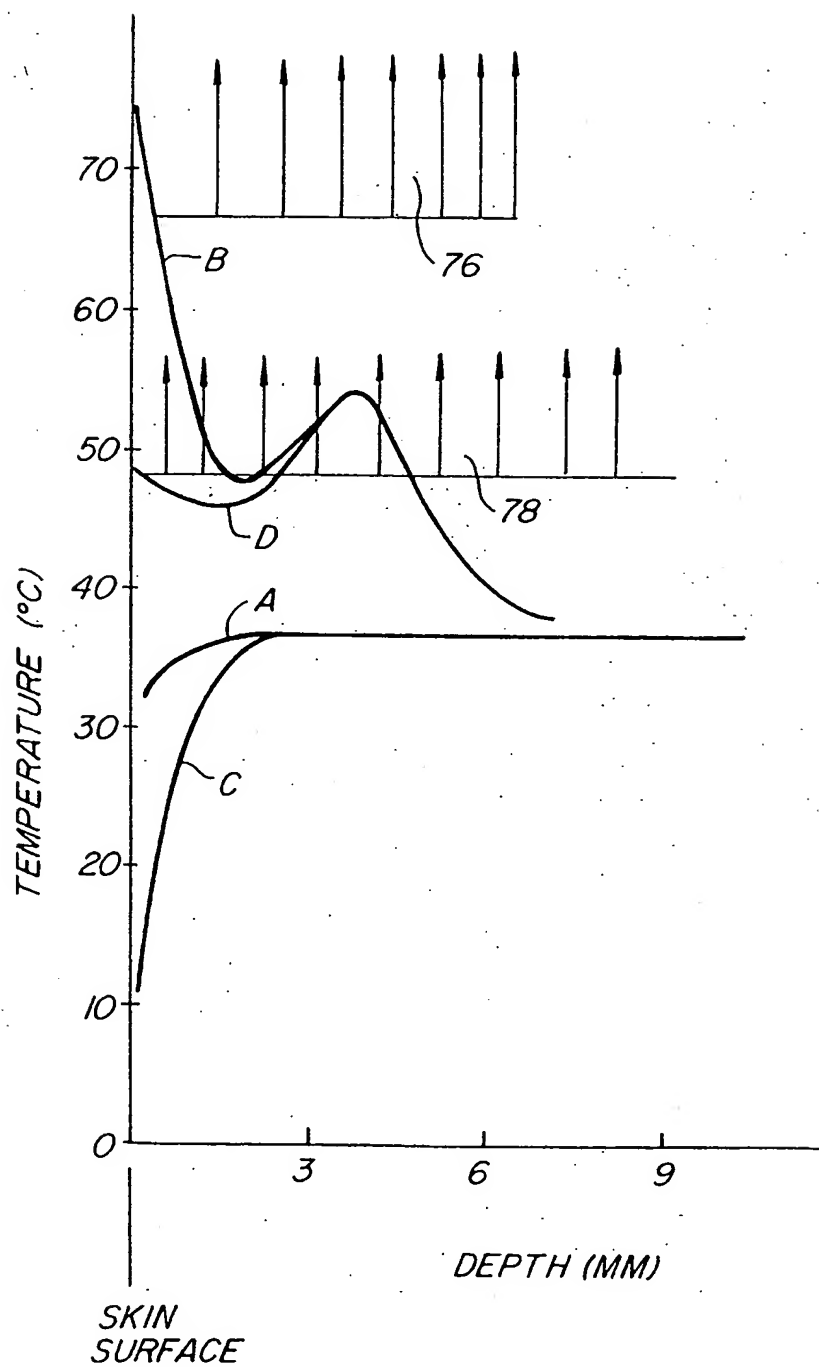


FIG. 7.

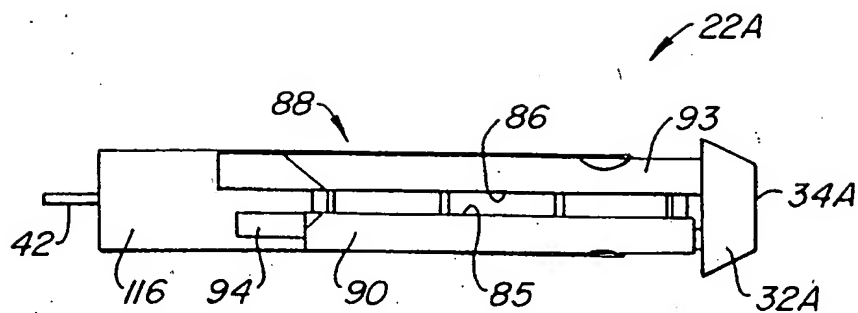


FIG. 8C.

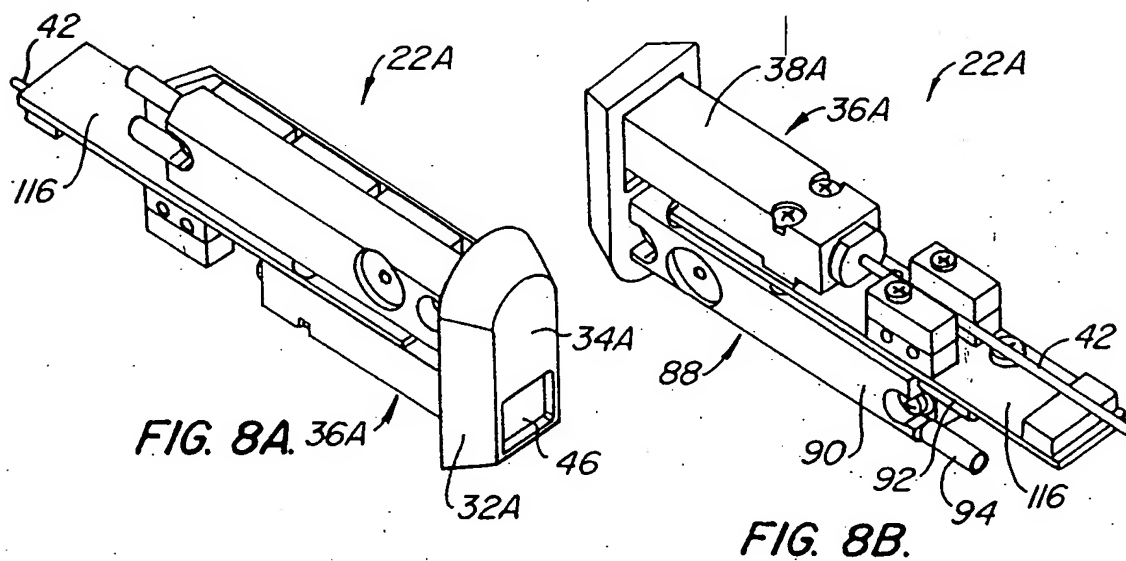


FIG. 8A.

FIG. 8B.

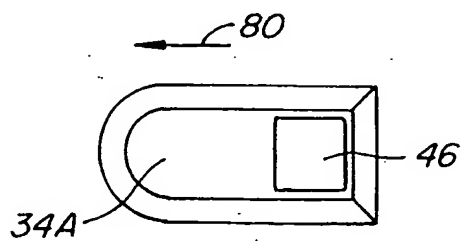


FIG. 8D.

7/8

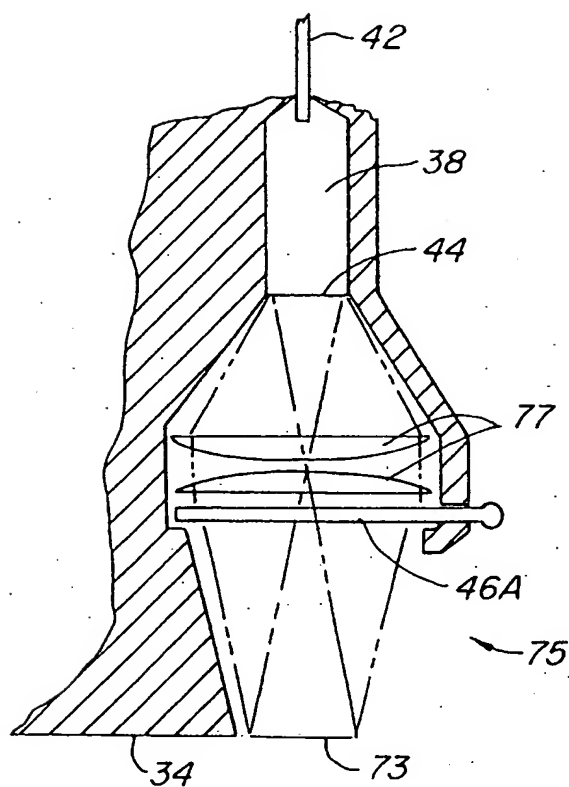


FIG. 9.

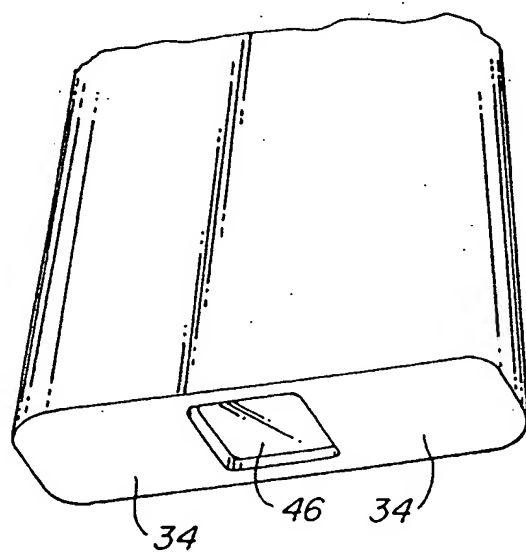


FIG. 10.

8/8

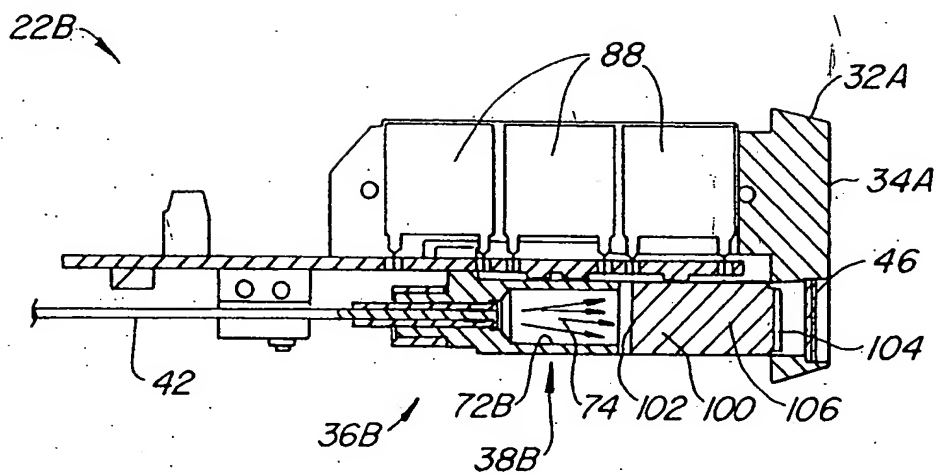


FIG. 11.

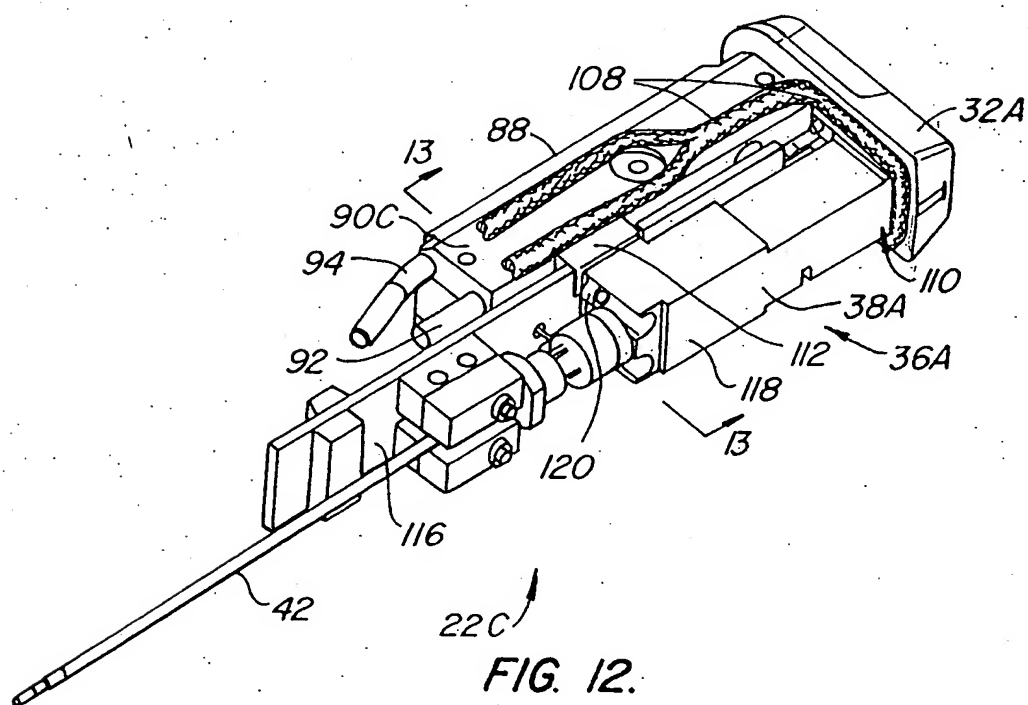


FIG. 12.

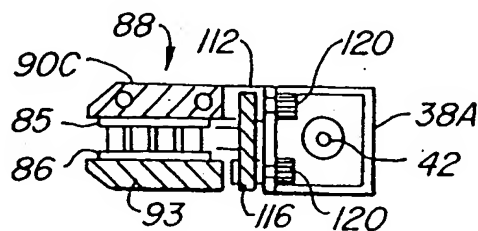


FIG. 13.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
21 September 2000 (21.09.2000)

PCT

(10) International Publication Number
WO 00/54685 A3

(51) International Patent Classification⁷: **A61B 18/20**

(21) International Application Number: **PCT/US00/06563**

(22) International Filing Date: **13 March 2000 (13.03.2000)**

(25) Filing Language: **English**

(26) Publication Language: **English**

(30) Priority Data:
09/270,118 15 March 1999 (15.03.1999) US
09/357,745 20 July 1999 (20.07.1999) US
09/393,830 10 September 1999 (10.09.1999) US

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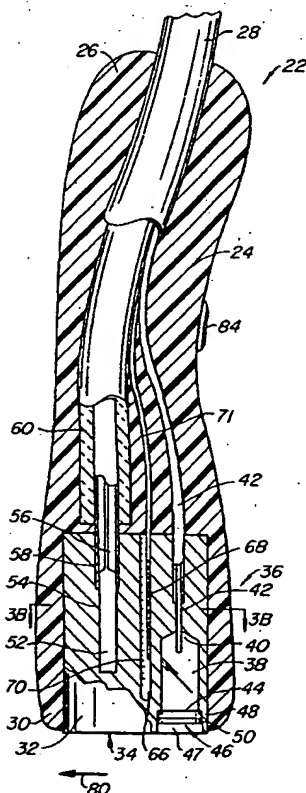
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(81) Designated States (*national*): AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU,

[Continued on next page]

(54) Title: **HAIR REMOVAL DEVICE AND METHOD**



(57) Abstract: A hair removal device (22) includes a cooling surface (34) which is used to contact the skin (6) prior to exposure to hair tissue-damaging laser light (74) passing from a radiation source (36) through a recessed window (46). The window is laterally offset from the cooling surface and is spaced apart from the cooling surface in a direction away from the patient's skin to create a gap between the window and the skin. The window preferably includes both an inner window (46) and an outer, user-replaceable window (48). The laser-pulse duration is preferably selected according to the general diameter of the hair.

WO 00/54685 A3



MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

(88) Date of publication of the international search report:
15 February 2001

Published:

— With international search report.

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 00/06563

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B18/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 98 51235 A (GEN HOSPITAL CORP ;PALOMAR MEDICAL TECHNOLOGIES I (US)) 19 November 1998 (1998-11-19)	23, 27, 30
A	page 18, line 27 -page 19, line 10; figure 5 page 11, line 5 - line 12 page 16, line 3 - line 5 page 21, line 7 - line 9 page 22, line 14 - line 16	1, 24, 28, 31, 33, 45, 48
Y	WO 98 24514 A (PALOMAR MEDICAL TECHNOLOGIES I) 11 June 1998 (1998-06-11)	23, 27, 30, 39-41, 45, 46
A	page 6, line 29 -page 7, line 9; figure 1 page 6, line 20 - line 22 page 7, line 4 - line 9	1, 25, 28
-/--		



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

24 October 2000

Date of mailing of the international search report

06 11 2000

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Mayer, E

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/06563

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 99 11324 A (BALLE PETERSEN OLAV ; ASAH BJARNE (DK); ASAH MEDICO A S (DK); DOLLE) 11 March 1999 (1999-03-11) page 41, line 4 - line 18; figure 14	1
Y	US 4 813 412 A (ABE KEIZO ET AL) 21 March 1989 (1989-03-21)	39-41, 45, 46
A	abstract column 5, line 9 - line 12	47
A	WO 99 07438 A (NEEV JOSEPH) 18 February 1999 (1999-02-18) page 20, line 1 - line 8	39, 40, 47

INTERNATIONAL SEARCH REPORT

Inte. ional application No.
PCT/US 00/06563

Box I. Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II. Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-22

Hair removal device with skin-cooling element and offset, recessed window for laser passage

2. Claims: 23-38

Hair removal device with skin-cooling element, offset window for laser passage and laser power input means.

3. Claims: 39-47

Method for hair removal comprising determining hair diameter and selecting pulse duration.

4. Claim : 48

Method for preparing to apply laser radiation with a hair removal device determining time intervals for cooling or between laser applications.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/06563

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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WO 9824514 A	11-06-1998	US 6015404 A	18-01-2000
WO 9911324 A	11-03-1999	AU 8851898 A EP 1009485 A US 6074382 A	22-03-1999 21-06-2000 13-06-2000
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WO 9907438 A	18-02-1999	AU 9017798 A	01-03-1999